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ATTORNEY DOCKET NO. 2003028-0048 (Ariad 331D USD1) MAR 12 2007  
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant: Schreiber & Crabtree  
Serial No.: 09/834,424  
Filed: April 13, 2001  
For: METHODS AND MATERIALS INVOLVING DIMERIZATION-MEDIATED  
REGULATION OF BIOLOGICAL EVENTS

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REPLY BRIEF UNDER 37 C.F.R. § 41.41

Appellant offers the present comments in Response to the remarks that were made in the Examiner's Answer mailed January 10, 2007 (the "Answer"). Most of the Examiner's remarks were restatements of previously-articulated positions, but some points were new; if a given item is not specifically discussed herein, then the Examiner has not presented new points of argument and/or Appellant relies on the arguments made in the Appeal Brief that was filed on September 28, 2006 (the "Appeal Brief").

For ease of presentation, Appellant's comments in this Reply Brief are organized according to the headings and numbered issues presented in the Appeal Brief. For the convenience of the Board, references to pages within the Examiner Answer are also included.

The deadline for filing a Reply Brief is March 10, 2007 which is a Saturday. Appellant thus submits that the present Reply Brief is timely filed on March 12, 2007 which is the following Monday.

**STATUS OF CLAIMS**

No amendments have been made since the Appeal Brief was filed. A listing of pending claims 8-29 was provided in a **Claims Appendix** to the Appeal Brief and still applies.

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U.S.S.N: 09/834,424  
4127976v1

Reference No.: 2003028-0048 (Ariad 331D USD1)

**GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

The grounds of rejection to be reviewed on appeal are:

- (1) Are claims 8-29 invalid for lack of written description under 35 U.S.C. § 112?
- (2) Are claims 8-16 and 18-27 anticipated under 35 U.S.C. § 102(b) by Wold (Methods Enzymology 11:617-640, 1966)?
- (3) Are claims 8-29 anticipated under 35 U.S.C. § 102(b) by Ji (Methods Enzymology 91:580-609, 1983)?

**ARGUMENT****Ground of Rejection 1:***Claims 8-29 are not Invalid for Lack of Written Description*

Claims 8-29 stand rejected for lack of written description. In the Answer, the Examiner continues to misapply the requirement for structural description that is required in order to satisfy the written description requirement in this case, e.g., see page 11 – “the skilled artisan cannot envision the *detailed chemical structure* of the encompassed genus of agents [...] and therefore conception is not achieved until reduction to practice has occurred”; page 12 – “[i]t is clear that the *structures* of agents to be prepared in the claimed method are not disclosed in the instant specification”; and page 13 – “[t]here must be a *particular structure(s)* that is disclosed to bind to a particular receptor-type such that the skilled artisan could envision that agents having the *structure(s)* could be used to oligomerized [sic] the particular receptor-type, thereby effecting a biological function.” It is clear from these comments that the Examiner is taking the position that non-peptidic agents recited in the present claims cannot be described unless their complete chemical structure is presented. This is not the law nor should it be.

Specifically, Appellant respectfully submits that this insistence on detailed structure cannot be reconciled with the written description standard that was articulated for antibodies in *Noelle v. Lederman*, 355 F.3d 1343 (Fed. Cir. 2004). As discussed in the Appeal Brief, the Federal Circuit clearly held that antibodies can be claimed by their binding affinity to an antigen without *any* structural description. *Id.* at 1349. The Examiner’s basis for distinguishing the antibodies of *Noelle* from the non-peptidic agents in this case is that “antibodies are large proteins having well-defined structure” (see page 10 of Answer). In the Appeal Brief, Appellant recognized that antibodies, as a class of molecules, have well defined structural characteristics and structural similarities. However, these characteristics and similarities are irrelevant to their *binding* capabilities. In fact, the portion of an antibody that is responsible for its binding attributes is referred to as the *variable* portion precisely because its amino acid sequence *differs* from that of other antibodies. It is not possible in advance to determine which variable region sequences will allow an antibody to bind to a particular antigen. The relevant structural characteristics of antibodies are therefore no more well defined than those of the claimed non-

peptidic agents. A skilled artisan could not have "envisioned the chemical structure of a genus of antibodies" without making them and yet the court in *Noelle* indicated that claims to such a genus are allowable. It is therefore apparent that reduction to practice and precise chemical structures are not necessarily required in order to satisfy the written description requirement.

For these reasons and those articulated in the Appeal Brief, Appellant respectfully submits that the present specification contains abundant description, and fully satisfies the written description requirement.

**Ground of Rejection 2:**

*Claims 8-16 and 18-27 are not Anticipated by Wold*

Claims 8-27 were rejected under 35 U.S.C. § 102(b) as being anticipated by Wold, *Methods Enzymology* 11:617-640, 1966 ("Wold"). The only dispute is over the broadest reasonable interpretation of the claim term "binds" in light of and consistent with the specification and the knowledge in the art. The claim term "binds" is used in the context of: "an agent that binds to two or more endogenous cell surface receptor molecules" (claims 8-16) or "an agent that binds to two or more endogenous protein mediators" (claims 18-27). The Examiner has argued that it is reasonable to interpret this term to cover *covalent bonding*, thereby bringing the teachings of Wold into play. Appellant respectfully submits that this interpretation is entirely unreasonable in light of (a) the common art usage of the term "binds" to refer to *non-covalent* associations (e.g., between an antibody and antigen or a receptor and a ligand); (b) the explicit teachings in the specification which point solely to *non-covalent* associations (binding affinities on page 11, lines 13-18; discussion of exemplary receptor binding moieties on page 13, lines 19-25; discussion of affinity assays for identifying receptor binding moieties on pages 14-19; etc.); and (c) the fact that the terms "*covalently linked*" are explicitly used in the claims to distinguish the covalent associations that exist within the agent from the non-covalent associations that exist between the agent and endogenous proteins.

On page 14 of the Answer, the Examiner dismisses Appellant's interpretation based on the sole fact that the binding affinities on page 11, lines 13-18 have no lower limit and do not therefore "eliminate compounds which would form a stronger bond, i.e., covalent bonds." Appellant is puzzled by this line of reasoning. Does the Examiner have any evidence that

binding affinities are used in the art to describe *covalent* bonds? If not, then on what basis would the skilled person decide that it would be *reasonable* to read this discussion of binding affinities as encompassing *covalent* bonding. Besides, the Examiner ignores the fact that the specification goes on to describe exemplary receptor binding moieties (page 13, lines 19-25) and affinity assays for identifying receptor binding moieties (pages 14-19) that only involve *non-covalent* associations. There is nothing in these teachings (or elsewhere in the specification) that could be reconciled with *covalent* bonding.

For these reasons and those articulated in the Appeal Brief, Appellant respectfully requests withdrawal of this rejection.

*Claim 17 is not Anticipated by Wold*

Appellant acknowledges the Examiner's withdrawal of claim 17 from this rejection (see page 15 of Answer).

**Ground of Rejection 3:**

*Claims 8-29 are not Anticipated by Ji*

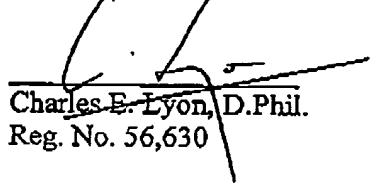
Claims 8-29 were rejected under 35 U.S.C. § 102(b) as being anticipated by Ji, Methods Enzymology 91:580-609, 1983 ("Ji"). Appellant's arguments here are identical to those presented above with respect to Wold and will not be reiterated.

**CONCLUSION**

Appellant again concludes with the belief that claims 8-29 are not anticipated by the prior art and are well supported by the specification. Allowance of the pending claims is earnestly requested.

Respectfully submitted,

Dated: March 12, 2007

  
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